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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/712,364	11/14/2000	Louis G. Lange III	93,473-G	5701

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EXAMINER

MAIER, LEIGH C

ART UNIT PAPER NUMBER

1623

DATE MAILED: 04/06/2004

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/712,364

Applicant(s)

LANGE ET AL.

Examiner

Leigh C. Maier

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Claim 12 has been amended. Claim 17 has been added. Claims 12-17 are pending. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Any objection or rejection not expressly repeated has been withdrawn.

Claim Rejections - 35 U.S.C. § 103

Claims 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over LANGE et al (WO 90/12579).

The invention has been amended to recite a method for lowering serum cholesterol in humans comprising administration of a high molecular weight sulfated polysaccharide (SPS) and a second compounds that reduces serum cholesterol levels. Dependent claims 13, 14, and 16 further limit the polysaccharide and the second compound. New claim 17 recites a similar method that is limited to the use of high molecular weight cellulose sulfate and lovastatin.

As discussed in the previous Office action, LANGE teaches the administration of SPSs, such as high molecular weight cellulose sulfate, which act as inhibitors of human cholesterol esterase, to lower serum cholesterol. See abstract, page 5, and example 4. The reference further suggests the use of said polysaccharides in combination with other agents having cholesterol-lowering activity. Particular agents suggested by the reference are ACAT inhibitors (see page 14, lines 19-25) and lovastatin (see page 15, lines 21-24). The use of the polysaccharides in combination with other agents is not specifically exemplified.

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The claims have been amended to further limit the SPS wherein said SPS comprises less than 5.0 wt% of SPSs having a molecular weight of less than 75 kD and containing less than 0.5 wt% inorganic sulfate. The LANGE is silent with regard to these physical characteristics of the SPSs therein. However, the reference clearly teaches that the cholesterol-lowering ability of these SPSs is a function of molecular weight with high molecular weight being most desired. See page 11, lines 6-10 and the paragraph bridging pages 12 and 13. The reference further teaches purification of the SPSs, including multiple re-precipitations and dialysis. See, for example page 21, lines 23-28.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have administered the disclosed SPSs taught by LANGE, in combination with other agents, such as ACAT inhibitors or lovastatin. The ordinarily skilled practitioner would have been motivated to obtain the combined effect of the agents in lowering serum cholesterol with a reasonable expectation of success, as LANGE had taught this method. It would have been further obvious to purify the SPSs taught in the reference to remove lower molecular weight SPSs and residual non-therapeutic reactants. With or without a specific teaching in the reference, one of ordinary skill would recognize the desirability of removing inorganic sulfates for an agent meant for pharmaceutical use in humans. Furthermore, the reference clearly teaches that the therapeutic activity is concentrated in the higher molecular weight products, providing motivation for removal of lower molecular weight ones. In the absence of unexpected results, it would be obvious to administer purified SPSs taught by LANGE for lowering cholesterol in humans. Applicant has demonstrated no therapeutic criticality in the specific physical properties of the SPSs.

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Applicant's arguments filed August 27, 2002 have been fully considered but they are not persuasive.

Applicant first contends that LANGE does not teach the need for purified SPSs. The examiner respectfully disagrees with the characterization of the reference. LANGE does teach purification of the SPSs by methods discussed above.

Applicant further argues that "the presence of free sulfate and low molecular weight sulfated polysaccharides are undesirable, even toxic." The removal of these entities would be obvious for reasons set forth above.

Finally Applicant contends "LANGE did not recognize that purified sulfated polysaccharides containing less than 5 weight percent of sulfated polysaccharides having a molecular weight less than 75,000 Daltons and containing less than 0.5 weight percent of inorganic sulfate are necessary for human use." If this is Applicant's position, then the products disclosed by LANGE must inherently have these characteristics because the reference clearly teaches that they are suitable for human use. Since the Office does not have the facilities for preparing the claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). It may be that there is some criticality in the purity levels recited in the instant claims, but none has been demonstrated. The examiner maintains that the purification of these products would be obvious in view of LANGE.

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 12 and 13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No. 6,632,801. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method claimed in '801 is a method for lowering cholesterol by administration of an SPS comprising all the limitations recited in the instant claims in combination with one or more cholesterol synthesis blockers. The more narrowly claimed method of '801 thus renders the instant invention to be obvious.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

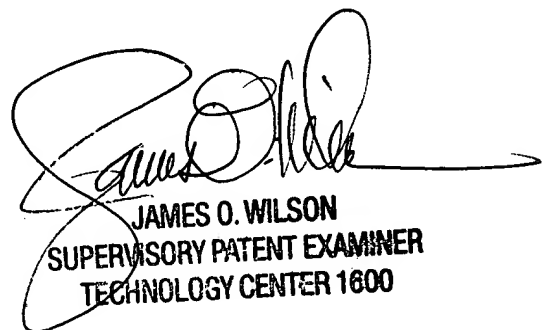
Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Wednesday, or Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (571) 272-0661, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 872-9306.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.

Leigh C. Maier
Patent Examiner
March 31, 2004



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